APR 17 2002 K020813

510(k) Premarket Notification
bioMérieux, Inc.
BacT/ALERT FA (Plastic) Culture Bottle

510 (k) Summary

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name:	bioMérieux, Inc.
Submitter's Address:	100 Rodolphe Street, Durham, North Carolina 27712
Submitter's Telephone:	(919) 620-2373
Submitter's Contact:	Ron Sanyal Ron Sanyal
Date 510(k) Summary Prepared:	March 8, 2002

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: BacT/ALERT FA Culture Bottle

Common or Usual Name: BacT/ALERT FA Culture Bottle

Classification Name: Microbial Growth Monitor

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: BacT/ALERT FA Glass Culture Bottle

(a)(4) **A description of the device.**

Device Description: The BacT/ALERT FA Plastic Culture Bottle was developed for the same intended use as the current BacT/ALERT FA Glass Culture Bottle, to provide suitable nutritional and environmental conditions for organisms commonly encountered in blood infections and normally sterile body fluids. An inoculated bottle is placed into the BacT/ALERT Microbial Detection Instruments where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT FA Bottle.

(a)(5) **A statement of the intended use of the device.**

Device Intended Use: BacT/ALERT FA Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and fungi) from blood and other normally sterile body fluids.

(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

The BacT/ALERT FA Plastic Culture Bottle utilizes the same detection technology as the BacT/ALERT FA Glass Culture Bottle. The similarities and/or differences with marketed device are listed in Table (a) (6) 1.

TABLE (a) (6) 1.

FEATURES	BACT/ALERT FA PLASTIC CULTURE BOTTLE	BACT/ALERT FA GLASS CULTURE BOTTLE (K992400)
Intended Use	Same	Same
Culture Bottle Material	Plastic	Glass
Product Code	MDB	MDB
Technology	Reflectance	Reflectance
Color change based on CO_2 production	YES	YES
Sensor	Emulsion	Emulsion
Indicator material	Xylenol Blue in Silicone Emulsion	Xylenol Blue in Silicone Emulsion
Growth of microorganisms	Same	Same
Instrument Used	BacT/ALERT Microbial Detection Systems	BacT/ALERT Microbial Detection Systems
Sample Source	Blood, Body Fluids	Blood, Body Fluids
Target Population	Adult	Adult

(b)1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.

Testing was performed to establish the performance characteristics of the new device including:

Seeded studies were performed on 23 organisms diluted in human blood and inoculated into the BacT/ALERT FA Plastic Culture bottle and the BacT/ALERT FA Glass Culture bottle.

(b)3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

The BacT/ALERT FA Plastic Culture Bottle was substantially equivalent to the BacT/ALERT FA Glass Culture Bottle based on recovery of low levels of the 23 microorganisms included in the study. Detection times were equivalent in both bottles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ron Sanyal, M. Pharm., CQE, RAC
Manager, Regulatory Affairs
Biomerieux, Inc.
100 Rodolphe Street
Durham, NC 27712

APR 17 2002

Re: k020813
Trade/Device Name: BacT/ALERT® FA Culture Bottle
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I
Product Code: MDB
Dated: March 8, 2002
Received: March 13, 2002

Dear Mr. Sanyal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K020813

Device Name: BacT/ALERT® FA Culture Bottle

Indications For Use:

BacT/ALERT® FA Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and fungi) from blood, and other normally sterile body fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Y. Poole

(Division Sign
Division of C ...atory Devices

510(k) Number K020813

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)